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APPLICATION NO. FILING DATE		FIRST NAMED INVENTOR			ATTORNEY DOCKET NO.	
09/015,469	01/29/98	KINGSTON		Н	04945000095	
ARNOLD B SILVERMAN		IM62/0706	٦	EXAMIN		
		« MELLOTT	8	SODER:	QUIST, A PAPER_NUMBER	
PITTSBURGH F	A 15219			1743	8	
				DATE MAILED	: 07/06/99	

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

	Application No. Applicant(s)							
Office Action Summary	09/015-469							
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-The MAILING DATE of this communication appears	on the cover sheet	beneath the c	orrespondence ad	idress				
P riod for Response	5	>						
A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SEMAILING DATE OF THIS COMMUNICATION.	ET TO EXPIRE	MONT	H(S) FROM THE					
 Extensions of time may be available under the provisions of 37 CFR 1. from the mailing date of this communication. If the period for response specified above is less than thirty (30) days, a If NO period for response is specified above, such period shall, by defa Failure to respond within the set or extended period for response will, b 	a response within the statuult, expire SIX (6) MONTH	tory minimum of t S from the mailing	hirty (30) days will be o	considered timely.				
Status								
Responsive to communication(s) filed on 5-17-	· 7 <i>7</i>			•				
☐ This action is FINAL .								
 Since this application is in condition for allowance except f accordance with the practice under Ex parte Quayle, 1935 			the merits is clos	sed in				
Disp sition of Claims								
(XClaim(s) 1-33	is/are	is/are pending in the application.						
Of the above claim(s)	is/are	_ is/are withdrawn from consideration.						
☐ Claim(s)	is/are	_ is/are allowed.						
KClaim(s) 1-33	is/are	_ is/are rejected.						
☐ Claim(s)	is/are	_ is/are objected to.						
□ Claim(s)		are subject to restriction or election requirement.						
Application Papers		Toquit	omone.					
☐ See the attached Notice of Draftsperson's Patent Drawing	Review, PTO-948.							
☐ The proposed drawing correction, filed on is ☐ approved ☐ disapproved.								
☐ The drawing(s) filed on is/are objected	ed to by the Examiner.							
☐ The specification is objected to by the Examiner.								
☐ The oath or declaration is objected to by the Examiner.								
Priority under 35 U.S.C. § 119 (a)-(d)								
 □ Acknowledgment is made of a claim for foreign priority und □ All □ Some* □ None of the CERTIFIED copies of th □ received. □ received in Application No. (Series Code/Serial Number □ received in this national stage application from the Inter 	ne priority documents h	nave been						
*Certified copies not received:	,							
Attachment(s)								
#Information Disclosure Statement(s), PTO-1449, Paper No. 1. Page 1. Pag	Interview Sumi	mary, PTO-413						
Notice of References Cited, PTO-892		☐ Notic of Informal Patent Application, PTO-152						
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948	Other							
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U. S. Patent and Trademark Office PTO-326 (Rev. 3-97)

Part of Paper No.___

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1. In response to the submission of the references that were lost by the office examiner has reconsidered the previous action and is sending this supplemental office action. The indicated allowability of claims 1 - 33 is withdrawn in view of the rejections which follow.

- 2. Claims 1 33 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: each species is spiked with a different isotope enriched spike as found on page 22, line 19 to page 23, line 3.
- 3. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 4 there are 4 equations with the symbols used not being completely defined for three of the equations.
- 4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- Claims 1 3, 5 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Kingston (US 5,414,259). In the patent Kingston teaches and claims a method of speciated isotope dilution mass spectrometry. The method of determining the concentration of a specie in a sample includes providing at least one predetermined, enriched isotope in the same speciated form as the species to be measured, spiking the sample containing the species to be measured, equilibrating the spiked species with the species to be measured, separating the species from the sample and subsequently determining the concentration of the species to be measured by employing isotopic element specie ratios. In one embodiment, a single speciated isotope spike is employed and, in others, two or more such spikes may be employed. In a preferred embodiment, time resolution chromatography is used to effect separation of these species from the sample and mass spectrometer is employed in determining isotopic elemental ratios. It is also preferred that a method be employed to determine if there was conversion from one species to another. In another embodiment, spiking of the several different isotopically enriched analogs of the same specie are added at various steps in the

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sampling procedure and the stability and integrity of the specie with respect to these processes is evaluated by mass spectrometric measurements of the various isotopic ratios. Chemical processes, extraction methods, dissolution procedures and storage procedures are evaluated. In another embodiment, speciated isotope dilution is used to determine the effect on species of various sample preparation methods and portions of sample preparation techniques. Extraction and separation procedures employ the technique to provide definitive evidence of accurate specie manipulation and provide for performance based measurement. Column 8 teaches an equation used in the mathematical deconvolution of the results. Column 10, beginning at line 5 and column 11 beginning at line 34, discuss the deconvolution of the results in the actual examples given. Columns 12 - 16 teach various separation methods, samples, and detection methods that can be used within the scope of the invention.

- 6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 7. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kingston as applied to claims 1 3 and 5 33 above, and further in view of Moore (newly cited and applied). Column 14 lines 26 54 teach the use of other algorithms to deconvolve the results. Kingston does not teach the equation of claim 4.

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In the paper Moore discusses internal normalization techniques for high accuracy isotope dilution analyses. Equations (1) and (2) on page 1085 are substantially similar to the equation found in column 8 of Kingston. The subsequent algebraic manipulations show that one of skill in the art is skilled to the point of combining equations to produce a single equation having information that is to be determined and can be measured in an experiment.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the equation of Kingston to account for conversion of the species as taught by Kingston because as shown by Moore one of skill in the art is capable of algebraic manipulation of mathematical equations to produce an equation which enables a desired quantity to be determined from variables that can be measured and properties which are known about a system.

8. The information disclosure statement has been considered. Those items that have been lined through are either of record or as with reference 34 did not contain anything which could be considered.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose telephone number is (703) 308-3989. The examiner can normally be reached Monday through Thursday and some Fridays from about 7:30 AM to about 5:00 PM.

For communication by fax to the organization where this application or proceeding is assigned, the appropriate fax phone numbers are (703) 305-7718, for Official papers prior to mailing of a final Office action; (703) 305-3599, for Official papers after mailing of a final Office action; and (703) 305-7719, for unofficial or draft papers. The above fax numbers will allow the papers to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Alen Sodergust June 30, 1999

ARLEN SODERQUIST PRIMARY EXAMINER